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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/482,653	01/13/2000	JOHN A. WELLS	70869-0078	7295

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EXAMINER	
COOLEY, CHARLES E	
ART UNIT	PAPER NUMBER
1723	15

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/482,653	Wells, Deceased et al.
Examiner	**Art Unit**
Charles Cooley	1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *3 Feb 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-37* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

OFFICE ACTION

Assignee

1. Receipt is acknowledged of a Consent of Assignee and Statement under 37 CFR 3.73(b) filed 29 OCT 2001.

Inventorship

2. Th requirement for proof of authority of the legal representative for deceased inventor John A. Wells is withdrawn in view of the new rules which no longer requires such proof.

Surrender of Patent

3. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178. The "Offer to Surrender Patent" filed 01 SEP 2000 is not a proper offer to surrender.

Reissue Oath/Declaration

4. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

a. It does not identify the citizenship of each inventor (37 CFR 1.63(a)(3)).

b. It does not state whether the inventor is a sole or joint inventor of the invention claimed (37 CFR 1.63(a)(3)).

c. It appears the name of the first inventor is actually --John R. Wells-- rather than "John A. Wells".

d. Is item (4) of the declaration missing data? (by any amendment on _____).

5. Claims 1-37 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Drawings

6. Requirements for drawings in reissue applications are found in 37 CFR 1.174 and MPEP 1413.

Specification

7. The abstract is acceptable.

8. The amended title of the invention is acceptable.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 28 and 29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Raccuglia et al. (USP 3,190,546).

The patent to Raccuglia et al. discloses a system in Figs. 8-11 comprising a centrifuge 212 with a rotor 214; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 166, 162, 141, 140, 168, 164, 153, 152 for transferring fluid between the chambers; a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions as seen in the solid and phantom positions of Figure 10; lid portions 120, 122; and access port 118. Although the adjective "sterile" is not considered a structural limitation as explained below, a primary objective of Raccuglia et al. is the separation of blood which would mandate the container being sterile. Accordingly, sterility is considered to be inherent characteristic of the container in Raccuglia et al.

11. Claims 25-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by McFarland (USP 3,642,163).

The patent to McFarland discloses a walled container (Fig. 1) comprising a first chamber 12 and a second chamber 14 adjacent the first chamber 12; a bridge 32 connecting a top portion of the first chamber 12 and a top portion of the second chamber 14; a removable lid 18; and access port (proximate 22 as fed from 48); means 22 inherently capable of maintaining sterility of the first and second chambers during addition or removal of liquids therefrom via supply and discharge means 46, 48, 50.

12. Claims 33 and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by McFarland (USP 3,642,163).

The patent to McFarland discloses a walled container (Fig. 3) comprising a first chamber 12A and a second chamber 14A; a bridge 62; lid 66; access ports 70; and separation disks 38.

13. Claims 33 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crippa (USP 4,026,433).

The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a lid 10; access ports (proximate 3 and 6); the bridge 4 being formed at the tops of the adjacent sidewalls of the chambers (Fig. 4). Although the adjective "sterile" is not considered a structural limitation as explained below, a primary objective of Crippa is providing a container for holding medical specimens to be analyzed which would mandate the container being sterile.

Accordingly, sterility is considered to be inherent characteristic of the container in Crippa.

14. Claims 33, 34, 35, and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Onishi (USP 4,294,372).

The patent to Onishi discloses a rigid walled container of a suitable material (Col. 3, lines 36-39) in Fig. 2 comprising a first chamber A and a second chamber B; a bridge 21a; a removable lid 23 or 25; access ports 22 and 24; the bridge 21a being formed at the tops of the adjacent sidewalls of the chambers (Fig. 2).

* * *

With regard to the above rejections, the operational and functional language of the claims (e.g., "such that a liquid can be transferred from the first chamber to the second chamber while the container is positioned at a predetermined angle" (claim 25)), has been considered but fails to impart or invoke any means or structure to the *apparatus* claims which defines over the applied prior art.

With regard to the claim language "sterile" or "sterility", the examiner's position is that the term "sterile" or "sterility" does not impart any specific structure to the container, but is perhaps a product by process limitation as to the manner in which the container is made or the manner in which the container is packaged (e.g., hermetically sealed to maintain sterility). However, the pending claims are strictly apparatus claims drawn to a centrifuge and/or container and no particular process for manufacturing the sterile

container, sterilizing the container, or packaging for the container is set forth that either imparts sterility to or maintains sterility of the container. Hence, it is not clear how the physical structure of the container changes to define over the prior art simply by labeling it "sterile". Since sterility itself is not considered to impart any unique structural features to define over the applied prior art, and since several of the prior art devices can reasonably be considered inherently sterile, the rejections are maintained.

Claim Rejections - 35 U.S.C. § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

17. Claims 28 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Raccuglia et al. (USP 3,190,546) in view of Le Veen (USP 3,221,741).

The patent to Raccuglia et al. discloses a system for processing fluids such a blood in Figs. 8-11 comprising a centrifuge 212 with a rotor 214; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 166, 162, 141, 140, 168, 164, 153, 152 for transferring fluid between the chambers; a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions as seen in the solid and phantom positions of Figure 10; lid portions 120, 122; and access port 118. Assuming, *arguendo*, that the chambers of the container of Raccuglia et al. are not sterile, the patent to Le Veen teaches that it was common practice as of 1962 to process blood in sterile chambers of containers (Col. 1, lines 9-15 and lines 40-44). It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the chambers of the container of Raccuglia et al. such that the chambers thereof are sterile as taught by Le Veen for the purpose of rendering the container free of microorganisms which could contaminate the materials in the container. Furthermore, the court has

held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, 109 USPQ 34, (CCPA 1956).

18. Claims 28 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Raccuglia et al. (USP 3,190,546) in view of Weber et al. (USP 3,228,444).

The patent to Raccuglia et al. discloses a system for processing fluids such a blood in Figs. 8-11 comprising a centrifuge 212 with a rotor 214; a walled container 110, 112 (Figs. 8-9) having a first chamber 114 and a second chamber 116; a bridge 166, 162, 141, 140, 168, 164, 153, 152 for transferring fluid between the chambers; a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions as seen in the solid and phantom positions of Figure 10; lid portions 120, 122; and access port 118. Assuming, *arguendo*, that the chambers of the container of Raccuglia et al. are not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the chambers of the container of Raccuglia et al. such that the chambers thereof are sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the chambers of the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court

has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

19. Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McFarland (USP 3,642,163) in view of Weber et al. (USP 3,228,444).

The patent to McFarland discloses a walled container (Fig. 1) comprising a first chamber 12 and a second chamber 14 adjacent the first chamber 12; a bridge 32 connecting a top portion of the first chamber 12 and a top portion of the second chamber 14; a removable lid 18; and access port (proximate 22 as fed from 48); means 22 inherently capable of maintaining sterility of the first and second chambers during addition or removal of liquids therefrom via supply and discharge means 46, 48, 50. McFarland does not explicitly discloses that the chambers of the container are sterile. Assuming, *arguendo*, that the chambers of the container of McFarland are not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the chambers of the container of McFarland such that the chambers thereof are sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

20. Claims 33 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McFarland (USP 3,642,163) in view of Weber et al. (USP 3,228,444).

The patent to McFarland discloses a walled container (Fig. 3) comprising a first chamber 12A and a second chamber 14A; a bridge 62; lid 66; access ports 70; and separation disks 38. McFarland does not explicitly discloses that the chambers of the container are sterile. Assuming, *arguendo*, that the chambers of the container of McFarland are not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the chambers of the container of McFarland such that the chambers thereof are sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

21. Claims 33 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Crippa (USP 4,026,433) in view of Weber et al. (USP 3,228,444).

The patent to Crippa discloses a walled container comprising a first chamber 1 and a second chamber 7; a bridge 4 (Fig. 4); a lid 10; access ports (proximate 3 and 6);

the bridge 4 being formed at the tops of the adjacent sidewalls of the chambers (Fig. 4). Crippa does not explicitly discloses that the container is sterile. Assuming, *arguendo*, that the chambers of the container of Crippa are not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the chambers of the container of Crippa such that the chambers thereof are sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

22. Claims 33, 34, 35, and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Onishi (USP 4,294,372) in view of Weber et al. (USP 3,228,444).

The patent to Onishi discloses a rigid walled container of a suitable material (Col. 3, lines 36-39) in Fig. 2 comprising a first chamber A and a second chamber B; a bridge 21a; a removable lid 23 or 25; access ports 22 and 24; the bridge 21a being formed at the tops of the adjacent sidewalls of the chambers (Fig. 2). Onishi does not explicitly discloses that the chambers of the container are sterile. Assuming, *arguendo*, that the chambers of the container of Onishi are not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been

obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the chambers of the container of Onishi such that the chambers thereof are sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

Allowable Subject Matter

23. Claim 30-32 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 251 and to include all of the limitations of the base claim and any intervening claims.

24. Claims 1-24 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 251.

Response to Amendment

25. Applicant's arguments filed 3 FEB 2003 have been fully considered but they are not deemed to be persuasive.

With regard to claim 25, the examiner disagrees that the prior art fails to show the recited means for maintaining sterility of the chambers as the elements 22 in

McFarland are inherently capable of performing such a function in the closed system of McFarland.

Applicant argues that claim 33 is not met by the prior art yet claim 33 stands unamended and the previous rejections of this claim are not believed to be in error. The previous rejections are therefore repeated and made final.

Amended claim 22 stands allowable over the prior art.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION. **ANY RESPONSE FILED AFTER THE MAILING DATE OF THIS FINAL REJECTION WILL BE SUBJECT TO THE PROVISIONS OF MPEP 714.12 AND 714.13.**

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Charles Cooley whose telephone number is ☎ (703) 308-0112.

28. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1700 receptionist whose telephone number is ☎ (703) 308-0651.

Dated: **27 February 2003**

Charles Cooley
Primary Examiner
Art Unit 1723